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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/613,903	07/11/2000	Heather J. Jordan	0942.4450001	1446

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EXAMINER

SISSON, BRADLEY L

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 02/12/2002 10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/613,903

Applicant(s)

JORDAN, HEATHER J.

Examiner

Bradley L. Sisson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 November 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) 28-34 and 38-42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-27 and 35-37 is/are rejected.
- 7) ☒ Claim(s) 35-37 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 July 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 1-27 and 35-37 in Paper No. 9, received 27 November 2001, is acknowledged. The traversal is on the ground(s) that the claims were previously examined in the parent application. This is not found persuasive because the examiner in charge of the subject application is not the same as that of the parent application and that each application is considered on its own merits.

The requirement is still deemed proper and is therefore made FINAL.

Location of Application

2. The location of the subject application has changed. The subject application is now located in Group 1630, Art Unit 1634.

Priority

3. If applicant desires priority under 35 U.S.C. 120 based upon a previously filed copending application, specific reference to the earlier filed application must be made in the instant application. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph. The status of non-provisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No. _____" should follow the filing date of the parent application. If

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a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

If the application is a utility or plant application filed on or after November 29, 2000, any claim for priority must be made during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2) and (a)(5). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A priority claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed claim for priority under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) a surcharge under 37 CFR 1.17(t), and (2) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Commissioner may require additional information where there is a question whether the delay was unintentional. The petition should be directed to the Office of Petitions, Box DAC, Assistant Commissioner for Patents, Washington, DC 20231.

Claim Objections

4. Claims 35-37 are objected to because of the following informalities: Said claims depend from non-elected claims 28, 29, and 31, respectively. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-27 and 35-37 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. As presently worded, the claimed composition and ladder can have an infinite upper size. Review of the specification, however, teaches that the upper limit of the composition/ladder is 12 kb. See, for example Table 1, page 20. See also page 19 where it is stated "the largest fragment generated being 12 kb (see Table 1)." Such disclosures do not reasonably describe nor reasonably suggest that applicant was in possession of a composition or ladder of nucleic acid fragments of any upper size. Similarly, the specification also shows that the smallest fragment produced and found useful was that of 100 bp. In contrast, the claimed composition and ladder encompasses monomer, dimers, etc., as well as nucleic acid sequences of infinite length. Additionally, the claimed composition and ladder encompass sequences that are made of RNA as well as being made of modified forms of nucleotides, e.g., PNA. The specification, however, shows that the composition and ladder are the result of cleavage of a plasmid (DNA), which in turn results in a series of DNA fragments. The specification has not been found to set forth an adequate written description of the claimed

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composition and ladder where it is comprised of other forms of nucleic acids and where such a composition/ladder has the requisite mass and intensity characteristics.

Applicant is urged to consider amending the claims such that they encompass only those embodiments adequately supported by the disclosure.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-27 and 35-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claim 1 is indefinite with respect to just what constitutes "substantially equivalent." To what are the strands being compared for equivalency, how is equivalency established and what are the metes and bounds of "substantially." As presently worded, the claim is drawn to "a composition or ladder" which seemingly speaks to a variety of sizes, yet the claim also requires that this same composition and ladder be "substantially equivalent." Such limitations seemingly cannot be used to describe the same compound or ladder, as they are contradictory. Claims 2-27 and 35-37, which depend from claim 1, fail to overcome this issue and are similarly rejected.

8. Claim 2 is indefinite with respect to what constitutes "substantially equal intensity." It is unclear how a molecule of nucleic acid has "intensity." Claim 2 is indefinite with respect to just how the intensity is to be determined. Assuming *arguendo*, that the "intensity" is in reference to staining and irradiation as used in a gel, it is unclear how a ladder or composition that is comprised of both single-stranded and double-stranded nucleic acids.

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9. Claim 24 is indefinite with respect to what constitutes "about the same."
10. Claim 25 is confusing with respect to "detectable labeled." Perhaps applicant had intended to refer to --detectably labeled--.
11. Claim 27 is confusing as to the metes and bounds to be ascribed to the term "about." As presently worded, the claimed composition or ladder can have "about 1 copy" of a variety of fragments. Given that the term "about" seemingly encompasses values both greater and less and the specified amount, such would seemingly allow for the claim to be met with none of the fragments necessarily being present as no absolute lower limit is set. Clarification is required.
12. Claims 1-27 and 35-37 are indefinite with respect to what constitutes the metes and bounds of "composition" and "ladder." It is not clear if the "composition" is to be interpreted as being one and the same as the "ladder," or whether they two are different in some respect. It is also unclear just how many nucleotide sequences are needed so to meet the minimum limitation of both the ladder and composition. Seemingly there would need to be a plurality of fragments present, however, claims 13 and 14, for example, indicate that the composition/ladder produces but a single band which implies that there need be but one type of fragment present.
13. Claims 1-27 and 35-37 are indefinite with respect to how the nucleic acid sequences can have the same mass and produce the same intensities, etc., when they can single stranded and double stranded sequences present in the same mixture and where they can be of the same length; see claim 16 where only "one" fragment needs to be single stranded.

Claim Rejections - 35 USC § 102

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

15. Claims 1-12, 15, 16, and 21-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Novagen 1997 Catalog.

16. The Novagen 1997 Catalog discloses "Perfect DNA Markers" and "Perfect RNA Markers" on pages 115 and 116, respectively, that read on the instant claims due to the Markers being prepared and supplied as equal mass per band. The DNA Markers are stated as being in kbp that are double stranded as kilobase pairs. The RNA Markers are described in terms of kb or kilobases in length, which speaks to their being single stranded.

Claim Rejections - 35 USC § 103

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

18. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
19. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
20. Claims 1-27 and 35-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Novagen 1997 Catalog in view of Invitrogen 1997 Product Catalog for highlighted bands therein for orientation.
21. While claims 35-37 depend from non-elected claims 28, 29, and 31, they have been considered only to the extent that they ultimately depend from claim 1 and not that they encompass non-elected embodiments.
22. See above for the basis of the rejection as it pertains to the disclosure of the Novagen 1997 Catalog.
23. Novagen 1997 Catalog does not teach highlighted bands for orientation.
24. The Invitrogen 1997 Product Catalog discloses highlighted bands for orientation in its 1 kb ladder and a 20 bp ladder.
25. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the disclosures of the Novagen and Invitrogen 1997 Catalogs so to

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arrive at a composition or ladder of nucleic acid fragments that are of the claimed range, can be either single-stranded or double-stranded nucleic acid sequences, have substantially the same relative mass and intensity. In view of the very nature of the products as being something that is commercially viable, the ordinary artisan would have been motivated to have combined these properties of the various products so to provide a product that filled this niche and would have had a reasonable expectation of success in so doing given the highly developed nature of the art.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (703) 308-3978. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Bradley L. Sisson
Primary Examiner
Art Unit 1634

bls
February 9, 2002